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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,777	07/07/2006	Michael J. Yaszemski	630666.00008	4282

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EXAMINER	
LISTVOYB, GREGORY	

ART UNIT	PAPER NUMBER
1711	

MAIL DATE	DELIVERY MODE
06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,777	YASZEMSKI ET AL.	
	Examiner	Art Unit	
	Gregory Listvoyb	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/27/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *14-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Wiggins ("the Design of bioabsorbable..."Thesis, Univ of S.Mississippi, 1992) herein Wiggins.

Wiggins discloses a copolymer comprising: caprolactone units and fumarate units (i.e. L-lactide-co-caprolactone fumarate, Abstract, p.2).

Claims 1-2 and 9-10 rejected under 35 U.S.C. 102(b) as being anticipated by Chung et al (Eur. Polym Journal, 39, 1817-1822) herein Chung.

Chung discloses a copolymer, containing PCL and fumarate moieties (p.1820 see PCL900/TMA/DPFDMA structure).

Regarding Claims 9 and 10, PCL 900 (polycaprolactone, having molecular weight in range of 500-10000 daltons) and fumaryl chloride participate in preparation of the above structure.

Claims 1, 2 and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Fisk et al (US patent 4082816) herein Fisk.

Fisk discloses a copolymer comprising caprolactone units and fumarate units, which obtained by polymerization of caprolactone and fumaric acid (Column 1, line 15 and Column 2, line 10).

Fisk does not disclose the above synthesis in his Examples. However, in this Examiner relies on the full disclosure of the Fick's patent.

Claims 1-8 and 11-13 rejected under 35 U.S.C. 102(b) as being anticipated by Breant et al (US patent 5747605) herein Breant.

Breant discloses a copolymer obtained from fumaric acid (Column 2, line 5) and polycaprolactone (PCL). Breant teaches that melting point of the product is 60C, where the copolymer injectable above melting point (column 2, line 65).

In reference to Claim 3 and 4, since melting point of Breant's copolymer is in the same range, as one of a copolymer of the application examined. Melting point Considering that the above copolymers have the same structure, it is the Examiner's position that they inherently have the same molecular characteristics (MWD, Mn and Mw).

In addition, according to Carother's equation

$$\bar{X}_n = \frac{1}{1-p},$$

where

- X_n is also the average chain length (in monomer units)
- $p = (N_0-N)/N_0$, where:

N_0 is the number of molecules present initially
N is the number of unreacted molecules at time t
p is also a measure of the extent of reaction

and MWD = 1+p for polycondensation polymers.

According to the above equation, theoretical MWD number is equal to 2 at full conversion of monomers. In practice, since monomers are not pure, typical MWD values of polycondensation-produced polymers are within the range of 2-4.

Regarding claim 7, since Breant 's PCL-fumarate has similar structure as the one in the Application, it is the Examiner's position that hardening point of Breant's copolymer is within 30-40C.

Claim Rejections - 35 USC § 103

Claims 9 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Kweong (Biomaterials 24(2003), 801-808), herein Kweong in combination with Chung.

Kweong discloses a novel degradable polylactone network for tissue engineering. In order to obtain the above structure, he uses PLC macromer with Mn=1250 and 2000 and chloride of ethylenically unsaturated acid.

Kweong does not teach a fumaril chloride as a starting component.

Chung discloses a reaction of fumaryl chloride with diglycol and PCL with methacryloyl chloride to produce an injectable, biodegradable interpenetrating network (Abstract, Fig 1 and Fig 2 and page 1820). Chung teaches that addition of the fumaric acid fragments allows the formulation of biodegradable polymer with good strength, viscosity and low polymerization shrinkage.

Therefore, it would be obvious to a person with ordinary skills in the art to use fumaril chloride in Kweong's polymers to achieve the above properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Listvoyb whose telephone number is (571) 272-6105. The examiner can normally be reached on 9am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregory Listvoyb
Examiner
Art Unit 1711

GL
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James J. Seidleck
Supervisory Patent Examiner
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